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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,547	11/30/2000	Harri Jukarainen	TUR-101	5767

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EXAMINER
PENG, KUO LIANG

ART UNIT	PAPER NUMBER
1712	11

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MEI

Office Action Summary	Application No.	Applicant(s)	
	09/701,547	JUKARAINEN ET AL.	
	Examiner	Art Unit	
	Kuo-Liang Peng	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/3/02 Amendment* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-44* is/are rejected.

7)☒ Claim(s) *23-39 and 42-44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Applicants' amendment filed on June 3, 2002 was received. Claims 1-22 are deleted. Claims 23-44 are added.

2. The application papers are objected to because they are not a permanent copy as required by 37 CFR 1.52(a). Reference is made to the formulae in Claim 42, which are not permanently printed on the original paper, instead they are on a small piece of paper which is tapped on the original paper.

Applicant is required either (1) to submit permanent copies of the identified parts or (2) to order a photocopy of the above identified parts to be made by the Patent and Trademark Office at applicant's expense for incorporation in the file. See MPEP § 608.01.

3. The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action (Paper No. 6).

4. The following Office Action is based on the scope of "lower alkyl group" being defined in the specification (page 4, line 30).

Claim Objections

5. Claims 23-39 and 42-44 are objected to because of the following informalities:

In lines 7-8 of Claim 23, should "polysiloxane units" be -- polysiloxane groups --, in order to be consistent with the terminology appearing in the rest of the claims?

In line 1 of Claim 29, should there be -- or matrix --, after "membrane"?

In line 1 of Claim 34, should "10" be -- 32 --?

In lines 4-5 of Claim 34, should "are a) partly free groups, which" be deleted?

In the formula in line 4 of Claim 42, should "r"" be -- R' --?

In line 54 of Claim 42, should "in that" be deleted?

In line 4 of Claim 43, should "R" and R"" be -- R' and R" --?

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 23-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the last two lines of Claim 23, "wherein there are at least three blocks in said elastomer composition" causes confusion because first of all, it is not clear as to what "blocks" refers to; secondly, it is not clear as to what component in said elastomer having "at least three blocks"?

In line 8 of Claim 40, "there being at least three blocks in said elastomer composition" causes confusion because first of all, it is not clear as to what "blocks" refers to; secondly, it is not clear as to what component in said elastomer having "at least three blocks"?

Claim 35 recites the limitation "the free R' and R"" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 40-44 recite the limitation "the elastomer or polymer" in line 5 of Claim 40. There is insufficient antecedent basis for this limitation in the claim.

In lines 12 and 14 of Claim 40, it is not clear as to what "in the absence of monomer" refers to because in method a), the "vinyl-functional polymer component" and the "hydride functional polymer" are monomers in the crosslinking reaction; and in method b), if there is no monomer, there is no reaction (i.e., crosslinking).

In Claims 40-41, none of method a) and method b) can necessarily result in a poly(alkylene oxide) containing siloxane elastomer because in the instant methods, the vinyl-functional polymer component and the hydride functional component in method a) or the "polymer component" in method b) do not necessarily contain poly(alkylene oxide).

In Claim 42, when T is $R^1O(CHRCH_2O)_mR^3$, the polysiloxane block copolymer "$T(AB)_xAT$" does not contain any alkenyl groups in the end of chain.

8. Claims 29-31 and 40-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the last line of Claim 29, the word "comprises" is not supported by the specification because the second elastomer may be a siloxane-based elastomer (page 3, line 11-12), i.e., the second elastomer does not contain any component other than the siloxane elastomer.

In the last three lines of Claim 40, "in the absence of monomer" is not supported by the specification.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 23-31 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 4,600,751).

With respect to Claims 23-24, Lee discloses a controlled-release membrane (col. 3, lines 3-12) potentially used for used in contact with humans (col. 7, lines 60-68) comprising A) a polysiloxane blocked and optionally grafted with poly(alkylene oxide) wherein the poly(alkylene oxide) blocks and grafts (if any) are one-end-capped with acryloxy groups and B) at least one substantially water insoluble aliphatically unsaturated organomonomer (col. 3, lines 15-63). In another embodiment, Lee further discloses a membrane containing only Component A) and containing no Component B) (Table I, Examples 1, 2 and 10). It is noted that the poly(alkylene oxide) blocks and poly(alkylene oxide) grafts are linked to the polysiloxanes via Si-C linkages (col. 3, lines 23-34 and col. 4, lines 65-68). It is further noted that Applicants' membrane or matrix is intended for use in controlled-release drugs. Therefore, to controlled-release drugs is an intention to use, which does not carry any patentability weight. Component A) can contain at least three blocks (col. 3, lines 20-56).

With respect to Claim 25, Lee further teaches that "d" can be 0 in the formula recited in col. 3, lines 23-34.

With respect to Claims 26-27, Lee further teaches that in the poly(alkylene oxide) grafts, "d" + "e" can be up to 30 (col. 3, lines 39-41 and col. 4, lines 65-68) and the number of siloxane repeating units in the polysiloxane can be up to 64 (i.e., "a" + "b") (col. 3, lines 36-37). R on the siloxane units can be a monovalent hydrocarbon of from 1 to 6 carbon atoms, which is free of aliphatic unsaturation. R' on the siloxane units can be methyl or phenyl (col. 3, lines 46-49).

With respect to Claim 28, Lee further teaches poly(alkylene oxide) blocks having the formula described in col. 3, lines 23-34, wherein "b" is 0; and "d" + "e" can be up to 30 (col. 3, lines 35-42).

With respect to Claims 29-31, Lee further teaches the use of a crosslinker (BCP-7) having the formula described in col. 17, lines 33-39 to crosslinked with BCP-1 (col. 9, lines 5-14). It is noted that the hydroxy groups in BCP-1 and BCP-7 are converted into acryloxy groups by IEM (col. 17, lines 49-51). It is noted that BCP-1 corresponds to "the first elastomer" in the instant claims and BCP-7 corresponds to "the second elastomer" in the instant claims, wherein BCP-1 and BCP-7 are crosslinked (i.e., "interlaced one inside the other").

With respect to Claim 39, Lee further teaches the use of a filler such as silica (col. 7, line 47).

With respect to Claims 40, Lee further teaches a method for the preparation of a siloxane elastomer which comprises poly(alkylene oxide) groups by crosslinked the siloxane elastomer with a peroxide (Examples 1-10 and col. 9, lines 27-33).

Responsive to arguments

11. Applicant's arguments filed on June 3, 2002 have been fully considered but they are not persuasive.

The Applicants' principal argument against the rejection is that A) when Lee's composition contains no monomer, the composition (e.g., Lee's Examples 1 or 2) is not an elastomer. As such, it is not suitable for making a matrix or membrane because "it has not been possible to measure for example the tensile strength of the elastomer". (Remarks, page 17, last paragraph); B) the present method has been limited in that there is not monomer present in the crosslinking reaction of the starting materials to form an elastomer (the hydride functional component of the present invention is not comparable to a monomer, since two hydride functional components do not react with each other)(Remarks, page 18, second paragraph).

Applicants' argument is not persuasive because of the following reasons:

With respect to A), Lee's Examples 1 and 2 are indeed elastomers (col. 9, lines 45-47), and they can be made into membranes (col. 1, lines 6-11). It is further noted that a composition weak in tensile strength does not necessarily mean that it is not capable of forming a membrane. On the contrast, the composition can be a membrane material as long as it can be processed (e.g., casted) into a film. Therefore, the tensile strength of the material is irrelevant.

With respect to B), first of all, it is noted that the term "in the absence of monomer" appears only in Claim 40 and dependent claims thereof, not the whole claimed invention. Secondly, as mentioned previously, it is not clear as to what "monomer" refers to. It seems that Applicants try to define "monomer" as those which can react with each other. However, it is well known that the hydride functional component containing Si-H groups can react with each

other, which is then considered as a monomer. For example, Meals (Meals et al., Silicons, Reinhold Publishing Corp., 1959, pages 115-116) teaches the self-condensation of Si-H containing compound). It is noted that Meals is applied here merely to show the hydride functional component is a monomer by Applicants' definition. Thirdly, the term "in the absence of monomer" is not supported by the specification originally filed.

12. The following Office Action is based on Claims 41-44 being further limiting Claim 40 by selecting method a) and incorporating the limitation in Claims 41-44, respectively.

13. Claims 32-38 and 41-44 would be allowable if rewritten to overcome claim objection and/or the claim rejection under 35 USC 112, first paragraph and/or second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Lee does not teach or suggest a) the blend recited in Claims 32-38; and b) the method of crosslinking a vinyl-functional polymer component and a hydride functional component recited in Claims 41-44.

14. Applicants' supplemental information disclosure statements filed on June 7, 2002 and July 9, 2002 have been considered. Applicants do not provide the corresponding Form 1449. Therefore, there is no signed Form 1449 to send to Applicants.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Kuo-Liang Peng

July 9, 2002

Robert Dawson
Supervisory Patent Examiner
Technology Center 1700